

111TH CONGRESS
1ST SESSION

S. _____

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

IN THE SENATE OF THE UNITED STATES

Mr. KYL (for himself and Mr. McCONNELL) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To protect all patients by prohibiting the use of data obtained from comparative effectiveness research to deny coverage of items or services under Federal health care programs and to ensure that comparative effectiveness research accounts for advancements in personalized medicine and differences in patient treatment response.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preserving Access to
5 Targeted, Individualized, and Effective New Treatments

1 and Services (PATIENTS) Act of 2009” or the “PA-
2 TIENTS Act of 2009”.

3 **SEC. 2. PROHIBITION ON CERTAIN USES OF DATA OB-**
4 **TAINED FROM COMPARATIVE EFFECTIVE-**
5 **NESS RESEARCH; ACCOUNTING FOR PERSON-**
6 **ALIZED MEDICINE AND DIFFERENCES IN PA-**
7 **TIENT TREATMENT RESPONSE.**

8 (a) IN GENERAL.—Notwithstanding any other provi-
9 sion of law, the Secretary of Health and Human Serv-
10 ices—

11 (1) shall not use data obtained from the con-
12 duct of comparative effectiveness research, including
13 such research that is conducted or supported using
14 funds appropriated under the American Recovery
15 and Reinvestment Act of 2009 (Public Law 111–5),
16 to deny coverage of an item or service under a Fed-
17 eral health care program (as defined in section
18 1128B(f) of the Social Security Act (42 U.S.C.
19 1320a–7b(f))); and

20 (2) shall ensure that comparative effectiveness
21 research conducted or supported by the Federal
22 Government accounts for factors contributing to dif-
23 ferences in the treatment response and treatment
24 preferences of patients, including patient-reported
25 outcomes, genomics and personalized medicine, the

1 unique needs of health disparity populations, and in-
2 direct patient benefits.

3 (b) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed as affecting the authority of the
5 Commissioner of Food and Drugs under the Federal
6 Food, Drug, and Cosmetic Act or the Public Health Serv-
7 ice Act.